

TSEAC Background Document

Bovine Brain, Spinal Cord, and Other Neurological Tissue in Foods, Drugs, and Cosmetics for Human Use

Bovine spongiform encephalopathy (BSE) is a transmissible, slowly progressive, fatal, degenerative disease affecting the central nervous system of cattle. BSE is one of a number of known transmissible spongiform encephalopathies (TSE), including scrapie in sheep, Creutzfeldt-Jakob disease (CJD) in humans, and chronic wasting disease in elk and deer. The disease is typically characterized in affected animals by increased apprehension, increased reaction to sound and touch, a swaying gait, and subtle behavioral changes, such as separation from the herd while at pasture, disorientation, staring, and excessive licking of the nose or flanks. The disease progresses to stumbling and falling, and ends with seizures, coma, and death. It is widely accepted that a new variant of human CJD (vCJD) results from consumption of the infectious agent that causes BSE, most likely through contaminated beef products.

To date, BSE has not been detected in the United States, in spite of an active ongoing BSE surveillance program since 1990. (There has been criticism as to whether the U.S. program is sufficiently rigorous to detect a rare case of BSE.) Nevertheless, the devastating consequences of BSE and transmission of vCJD in Europe have prompted U.S. regulatory agencies to seriously consider the potential transmission of BSE in this country.

In cattle naturally infected with BSE (e.g., via contaminated feed), the BSE agent has been found only in brain tissue, the spinal cord, and the retina. Additionally, in experimentally infected cattle, the distal ileum, bone marrow, dorsal root ganglion, and trigeminal ganglion have been found to be infective. BSE infectivity is generally only detected in tissues when the animal is over 24 months of age, with the exception of the distal ileum, which has been found to be infective in animals as young as 6 to 18 months. However, since muscle has never been shown to contain the infectious agent in any TSE, whatever the affected species, transmission of vCJD to humans most probably results from consumption of beef products contaminated by bovine central nervous system (CNS) tissue and related spinal tissue. Contamination of beef products and other foods with bovine CNS tissue and related spinal tissue may occur in many ways, including the following:

- (1) dissemination of CNS tissue (as emboli) throughout the circulatory system of stunned cattle as a result of certain stunning methods,
- (2) cross contamination of muscle tissue with brain or spinal cord tissue by saws or other tools used during slaughter,
- (3) the presence of spinal tissue (residual spinal cord and dorsal root ganglia) in meat produced using Advanced Meat Recovery systems or paste of “Mechanically Separated (Beef)” meat food product (particularly from compressed vertebral bones),
- (4) inclusion of dorsal root ganglia in cuts of meat containing vertebral tissue (e.g., T-bone steaks),

(5) use of beef extracts from rendered vertebral columns (e.g., soup stock) in foods or dietary supplements, or

(6) distal ileum used to manufacture sausage casings.

Additionally, bovine CNS and other neurological tissue may be intentionally consumed as a food, dietary supplement, or an ingredient in one of these. Drugs and cosmetics containing bovine-derived ingredients may also be of concern because these products can enter the body through the mouth, nose, eye, or, potentially, through abraded skin. Some drugs may be administered directly into the bloodstream by injection or implanted in the body. In addition, products derived from cattle rendered without inspection (e.g., cattle that died on the farm or are dying) may be used in products not for human consumption.

The analytical tests currently available to identify animals in the pre-clinical phase of BSE can only identify positive animals if they are within 3 months of displaying signs of the disease. Thus, these tests are not adequate for screening purposes, since the disease typically exhibits a long (2-8 years) incubation period, following oral exposure, during which animals that appear normal may be infectious. There are currently no analytical tests practical for large-scale use to detect the infectious agent in muscle, organs, tissues, or in products containing muscle, organs, tissues or their components as ingredients. There are validated tests for the detection of CNS tissues in boneless meat product.

Under the Public Health Service Act, FDA has the authority to make and enforce such regulations as are necessary to prevent the introduction, transmission, or spread of a communicable disease. Under the authority of the Federal Food, Drug, and Cosmetic Act, FDA is charged with ensuring the safety of cosmetics, all domestic and imported food and feed (except most meat, poultry and egg products, which are regulated by the U.S. Department of Agriculture) and the safety and effectiveness of drugs (including animal drugs), vaccines, biologics, blood products, and medical devices. FDA uses existing scientific data, expert opinion, and risk assessment in developing science-based food safety policies. Because bovine brains and other neurological tissues could constitute a potential food, drug, or cosmetic safety hazard, FDA seeks the input of the TSE Advisory Committee in determining the benefit, if any, of restricting the use of bovine neurological tissues and products containing, contaminated with, or manufactured from these tissues in foods, drugs, and cosmetics for human use.